UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,262	11/25/2003	Jeffrey E. Fetterman	125889.101	6372

7590 12/07/2009

Pepper Hamilton LLP
One Mellon Center
5oth Floor
500 Grant Street
Pitttsburgh, PA 15219

EXAMINER	
RAJ, RAJIV J	
ART UNIT	PAPER NUMBER
3686	

MAIL DATE	DELIVERY MODE
12/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,262	FETTERMAN ET AL.	
	Examiner	Art Unit	
	RAJIV J. RAJ	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42 and 51-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42 and 51-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. This action is in reply to the amendment filed on 23 September 2009.
2. Claims 1& 51-54 have been amended.
3. Claims 1-42 & 51-54 are currently pending and have been examined.

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-42 are rejected under 35 U.S.C. 101 based on Supreme Court precedent, and recent Federal Circuit decisions, a § 101 process must (1) be tied to a machine or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. Diamond v. Diehr, 450 U.S. 175, 184 (1981); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978); Gottschalk v. Benson, 409 U.S. 63, 70 (1972); Cochrane v. Deener, 94 U.S. 780,787-88 (1876). The

process steps in claims (1-42) are not tied to a machine nor do they execute a transformation. Thus, they are non-statutory.

7. **Software per se**:

Under the broadest reasonable interpretation standard, claim 51 recites a "Logic" only. "Logic" claimed as computer listings per se, i.e., the descriptions or expressions of the programs, are not physical 'things.' They are neither computer components nor statutory processes, as they are not 'acts' being performed." MPEP §2106.01 I. Because the claims recite only abstractions that are neither "things" nor "acts," the claims are not within one of the four statutory classes of invention. Because the claims are not within one of the four statutory classes of invention, the claims are rejected under 35 U.S.C. §101.

In this particular case, claim 51 recites "Logic". Because Applicant's specification does not lexicographically define "Logic", Examiner uses the broadest reasonable interpretation to define "Logic" as hardware. Thus, Examiner interprets claim 51 as requiring a hardware component for "Logic"; therefore, claim 51 is not directed to software alone.

Note that claim 51 recites "Logic." Because Applicant's specification does not lexicographically define "Logic", Examiner uses the broadest reasonable interpretation to define "Logic" as hardware. Thus, Examiner interprets claim 51 as requiring a hardware component for "Logic"; therefore, claim 51 are not directed to software alone.

Under the broadest reasonable interpretation standard, claim 52 recites a "processor" & "memory". "Processor" & "memory " claimed as computer listings per se, i.e., the descriptions or expressions of the programs, are not physical 'things.' They are neither computer components nor statutory processes, as they are not 'acts' being performed." MPEP §2106.01 I. Because the claims recite only abstractions that are neither "things" nor "acts," the claims are not within one of the four statutory classes of invention. Because the claims are not within one of the four statutory classes of invention, the claims are rejected under 35 U.S.C. §101.

In this particular case, claim 52 recites a "processor" & "memory". Because Applicant's specification does not lexicographically define a "processor" & "memory", Examiner uses the broadest reasonable interpretation to define a "processor" & "memory" as hardware. Thus, Examiner interprets claim 52 as requiring a hardware component for a "processor" & "memory"; therefore, claim 52 is not directed to software alone.

Note that claim 52 recites a "processor" & "memory". Because Applicant's specification does not lexicographically define a "processor" & "memory", Examiner uses the broadest reasonable interpretation to define a "processor" & "memory" as hardware. Thus, Examiner interprets claim 52 as requiring a hardware component for a "processor" & "memory"; therefore, claim 52 are not directed to software alone.

Under the broadest reasonable interpretation standard, claim 53 recites a "processor" & "storage media". "Processor" & "media " claimed as computer listings per se, i.e., the descriptions or expressions of the programs, are not physical 'things.' They are neither computer components nor statutory processes, as they are not 'acts' being performed." MPEP §2106.01 I. Because the claims recite only abstractions that are neither "things" nor "acts," the claims are not within one of the four statutory classes of invention. Because the claims are not within one of the four statutory classes of invention, the claims are rejected under 35 U.S.C. §101.

In this particular case, claim 53 recites a "processor" & "media". Because Applicant's specification does not lexicographically define a "processor" & "media", Examiner uses the broadest reasonable interpretation to define a "processor" & "media" as hardware. Thus, Examiner interprets claim 53 as requiring a hardware component for a "processor" & "media"; therefore, claim 53 is not directed to software alone.

Note that claim 53 recites a "processor" & "media". Because Applicant's specification does not lexicographically define a "processor" & "media", Examiner uses the broadest reasonable interpretation to define a "processor" & "media" as hardware. Thus, Examiner interprets claim 53 as requiring a hardware component for a "processor" & "media"; therefore, claim 53 are not directed to software alone.

Under the broadest reasonable interpretation standard, claim 54 recites a "computer means". "Computer means". " claimed as computer listings per se, i.e., the descriptions or expressions of the programs, are not physical 'things.' They are neither computer components nor statutory processes, as they are not 'acts' being performed." MPEP §2106.01 I. Because the claims recite only abstractions that are neither "things" nor "acts," the claims are not within one of the four statutory classes of invention. Because the claims are not within one of the four statutory classes of invention, the claims are rejected under 35 U.S.C. §101.

In this particular case, claim 54 recites a "computer means". Because Applicant's specification does not lexicographically define a "computer means" , Examiner uses the broadest reasonable interpretation to define a "computer means" as hardware. Thus, Examiner interprets claim 54 as requiring a hardware component for a "computer means"; therefore, claim 54 is not directed to software alone.

Note that claim 54 recites a "computer means". Because Applicant's specification does not lexicographically define a "computer means", Examiner uses the broadest reasonable interpretation to define a "computer means" as hardware. Thus, Examiner interprets claim 54 as requiring a hardware component for a "computer means"; therefore, claim 54 are not directed to software alone.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. In response to Applicant's amendments the 112 2nd rejection of claims 15 & 21 has been withdrawn.

10. In response to Applicant's amendments the 112 2nd rejection of claim 11 has been withdrawn.

11. In response to Applicant's amendments the 112 6th rejection of claim 53 has been withdrawn.

12. Claims 1,29,30 & 51-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terms "adverse events" & "adverse side effects" in the claims renders the claims indefinite. It is not clear what constitutes "adverse events" & "adverse side effects". For example, what is deemed "adverse events" & "adverse side effects" by one of ordinary skill in the art may not necessarily be deemed "adverse events" & "adverse side effects" by another person of ordinary skill in the art.

13. Claims 1,29,30 & 51-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "logical" in the claims

renders the claims indefinite. It is not clear what constitutes a "logical" hazard assessment. For example, what is deemed a "logical" hazard assessment by one of ordinary skill in the art may not necessarily be deemed a "logical" hazard assessment by another person of ordinary skill in the art.

14. Claims 1 & 51-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “adequate” in the claims renders the claims indefinite. It is not clear what constitutes “adequate”. For example, what is deemed “adequate” by one of ordinary skill in the art may not necessarily be deemed “adequate” by another person of ordinary skill in the art.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. Claims 1, 7-21, 23-25, 29-36, 51-52 & 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayaud (US 2002/0042725 A1) (hereinafter Mayaud) in view of Ghouri (US 2004/0049506 A1) (hereinafter Ghouri) in further view of Applicant's Own Admission (hereinafter AOA).

Claim 1

Mayaud as shown, discloses the following limitations:

- *identifying a medication use process associated with a pharmaceutical product;* (see at least Mayaud [0269-0270] Fig:6 Items:110-120 & related text)
- *designing a risk management intervention program to manage said adverse events;* (see at least Mayaud [0033], Fig:15 Items:182-188 & related text)

Mayaud does not disclose the following limitations, however Ghouri, as shown does:

- *identifying, characterizing and ranking, by a processor, adverse events caused by using the pharmaceutical product;* (see at least Ghouri [0089-0093])
- *determining, by the processor, whether the medication use process will be adequate to protect patients from experiencing adverse side effects;* (see at least Ghouri Claims:1-2, 18-19)
- *based on the determination . . . ;* (see at least Ghouri Claims:1-2, 18-19)

- *identifying one or more multiple redundant interventions for each failure mode;* (see at least Ghouri Claims:4,7-13)
- *automatically quantifying, by the processor, the potential effect of said failure mode to create a pharmaceutical hazard score, wherein said hazard score considers the severity and frequency of occurrence of the effects of said failure;* (see at least Ghouri [0083-0090])
- *automatically conducting, by the processor, a logical hazard assessment of said failure modes found to have a high hazard score to evaluate the need to mitigate the effect of said failure modes;* (see at least Ghouri [0083-0090])
- *based on the logical hazard assessment . . . ;* (see at least Ghouri [0083-0090])

It would have been obvious to one of ordinary skill in the art to add the feature of Ghouri into Mayaud. One of ordinary skill in the art would have added this feature into Mayaud with the motivation to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products. (see at least Ghouri Column:3 Lines:10-67 Column:4 Lines:1-42)

Applicant's limitation, in claim 1: *wherein the medication use process is implemented to protect patients from a risk of experiencing adverse side effects associated with use of the pharmaceutical product;* is merely a recitation of the intended use of the claimed invention and is not given patentable weight to the

extent that it imparts limitations to the invention, which are met by Beaulieu/Silva-Craig. (See MPEP 2111.04) A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicant's limitation, in claim 1: *to evaluate the need to mitigate the effect of said failure modes;*, is merely a recitation of the intended use of the claimed invention and is not given patentable weight to the extent that it imparts limitations to the invention, which are met by Dempsey. (See MPEP 2111.04) A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Mayaud/Ghouri does not disclose the following limitation, however AOA, as shown does:

- *identifying potential failure modes where the medication use process will not be adequate to protect patients from experiencing adverse side effects;* (see at least AOA [0002-0006])

It would have been obvious to one of ordinary skill in the art to add the features of AOA into Mayaud/Ghouri. One of ordinary skill in the art would have added these features into Mayaud/Ghouri with the motivation to provide an

improved process for identifying and creating an ideal prescription plan in order to provide improved health care to patients.

Claim 7

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1. Ghouri further discloses the following limitation:

- *analyzing available data from animal, toxicology, pharmacokinetic, pharmacodynamic and pharmacogenomic studies of the pharmaceutical product;* (see at least Ghouri [0019-0020])

It would have been obvious to one of ordinary skill in the art to add the feature of Ghouri into Mayaud/Ghouri/AOA. One of ordinary skill in the art would have added this feature into Mayaud/Ghouri/AOA with the motivation to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products. (see at least Ghouri Column:3 Lines:10-67 Column:4 Lines:1-42)

Claim 8

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1. Ghouri further discloses the following limitation:

- *analyzing existing clinical safety data for the pharmaceutical product;* (see at least Ghouri [0019-0020])

It would have been obvious to one of ordinary skill in the art to add the feature of Ghouri into Mayaud/Ghouri/AOA. One of ordinary skill in the art would have added this feature into Mayaud/Ghouri/AOA with the motivation to more

accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products. (see at least Ghouri Column:3 Lines:10-67 Column:4 Lines:1-42)

Claim 9

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1. Ghouri further discloses the following limitation:

- *analyzing risks identified in similar products;* (see at least Ghouri [0013, 0019-0020])

It would have been obvious to one of ordinary skill in the art to add the feature of Ghouri into Mayaud/Ghouri/AOA. One of ordinary skill in the art would have added this feature into Mayaud/Ghouri/AOA with the motivation to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products. (see at least Ghouri Column:3 Lines:10-67 Column:4 Lines:1-42)

Claim 10

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1. Mayaud further discloses the following limitation:

- *graphically depicting the medication use process of prescribing, dispensing, and administering the pharmaceutical product as a plurality of steps;* (see at least Mayaud Fig:3-15 & related text)

- *identifying subprocesses for each of said steps;* (see at least Mayaud Fig:1-4,6, 15 Items:10, 45, 110 & 182 & related text)

Claim 11

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1. Mayaud further discloses the following limitation:

- *identifying one or more processes of prescribing, dispensing or administering the pharmaceutical product or a combination thereof;* (see at least Mayaud Fig:3 Items:54-70, 98-102 & related text)

Claim 12

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1. Ghouri further discloses the following limitation:

- *utilizing a pharmaceutical severity scale; and utilizing a pharmaceutical frequency of occurrence scale;* (see at least Ghouri Fig:2 & related text)

It would have been obvious to one of ordinary skill in the art to add the feature of Ghouri into Mayaud/Ghouri/AOA. One of ordinary skill in the art would have added this feature into Mayaud/Ghouri/AOA with the motivation to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products. (see at least Ghouri Column:3 Lines:10-67 Column:4 Lines:1-42)

Claim 13

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1.

Mayaud further discloses the following limitation:

- *analyzing the criticality and detectability of the failure mode to determine the need to mitigate the failure mode;* (see at least Mayaud [0240-0241], [0245-0246])

Claim 14

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 13.

Mayaud further discloses the following limitation:

- *analyzing existing risk control measures for the failure mode to determine whether the existing risk control measures mitigate the failure mode without further intervention;* (see at least Mayaud [0240-0241], [0245-0246])

Claim 15

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 13.

Mayaud further discloses the following limitation:

- *education, communications and/or control measures in redundant combinations and incorporating adult learning principles designed to be readily implemented in order to reduce the incidence and consequences of said failure modes;* (see at least Mayaud [0240-0246])

Claim 16

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1.

Mayaud further discloses the following limitation:

- *a primary intervention targeted to reduce the incidence of each failure mode;* (see at least Mayaud [0240-0246])

Claim 17

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1.

Mayaud further discloses the following limitation:

- *one or more redundant backup interventions to decrease the occurrence of and/or mitigate the consequences of failure of the primary intervention;* (see at least Mayaud [0240-0246])

Claim 18

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1.

Mayaud further discloses the following limitation:

- *distributing interventions to multiple end users, wherein the multiple end users are selected from the group consisting of physicians, health care providers, caregivers and patients;* (see at least Mayaud [0240-0246] Fig:16 Items:201-214 & related text)

Claim 19

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1.

Mayaud further discloses the following limitation:

- *coordinating care among multiple end users, wherein the multiple end users are selected from the group consisting of physicians, health care providers, caregivers and patients;* (see at least Mayaud Fig:16 Items:201-216 & related text)

Claim 20

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1. Mayaud further discloses the following limitation:

- *tailoring said risk management intervention program to local medical practice standards and needs including, but not limited to the delegation of primary responsibility for the program from physician to support staff;* (see at least Mayaud [0113-0124])

Examiner notes that all claim language, in claim 20, following *but not limited to . . .* is not given any patentable weight. This claim language fails to further limit or define applicant's invention.

Claim 21

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1. Mayaud further discloses the following limitation:

- *designating interventions that transfer medical knowledge and reinforce knowledge retention;* (see at least Mayaud [0019-0035] Fig:16 Items:201-216 & related text)

Claim 23

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1. Mayaud further discloses the following limitation:

- *developing a risk communication curriculum to communicate risk to an end user, wherein the end user is selected from the group consisting of physicians, pharmacists, health care providers, caregivers and patients;* (see at least Mayaud Fig:16 Items:201-216 & related text)

Claim 24

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1. Mayaud further discloses the following limitation:

- *transferring know-how, insights, techniques, methods, and processes from more experienced physicians and support staff to less experienced physicians and support staff;* (see at least Mayaud Fig:16 Items:201-216 & related text)

Claim 25

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1. Mayaud further discloses the following limitation:

- *utilizing existing interventions and tools developed by one or more of clinicians, peer to peer forums, clinical consultations and preceptorships;* (see at least Mayaud Fig:16 Items:201-216 & related text)

Claim 29

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1.

Mayaud further discloses the following limitation:

- *utilizing a professional support network for the collection and management of data associated with the adverse events;* (see at least Mayaud Fig:16 Items:200-218 & related text)

Claim 30

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 29.

Mayaud further discloses the following limitation:

- *occurrences of the adverse events;* (see at least Mayaud Fig:16 Items:200-218 & related text)

Claim 31

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1.

Mayaud further discloses the following limitation:

- *educational resources for delivering information regarding prescribing, dispensing, and use of pharmaceutical product;* (see at least Mayaud Fig:3,12,15 Items:138-142,182-188 & related text)

Claim 32

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 31.

Mayaud further discloses the following limitation:

- *identification of control measures for the pharmaceutical product;* (see at least Mayaud [0240-0246])

Claim 33

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 31.

Mayaud further discloses the following limitation:

- *classes to instruct an end user on said control measures;* (see at least Mayaud [0300] Fig:11 & related text)

Claim 34

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 31.

Mayaud further discloses the following limitation:

- *educational resources are available by electronic, written, audio, or video communication;* (see at least Mayaud Fig:16 Items:200-218 & related text)

Claim 35

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1.

Mayaud further discloses the following limitation:

- *implementing distribution controls wherein said distribution controls manage the availability of the pharmaceutical product;* (see at least Mayaud Fig:16 Items:200-218 & related text)

Claim 36

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 35.

Mayaud further discloses the following limitation:

- *limiting availability of the pharmaceutical product to a single source;* (see at least Mayaud [0346-0359], Fig:16 Item:206 & related text)

Claim 51

Mayaud as shown, discloses the following limitations:

- *a logic;* (see at least Mayaud Claim:21-22)
- *identify a medication use process associated with the pharmaceutical product;* (see at least Mayaud [0269-0270], Fig:6 Item:110-120 & related text)
- *design a risk management program to manage said adverse events;* (see at least Mayaud [0033], [0240-0246], Fig:15 Items:182-188 & related text)

Mayaud does not disclose the following limitations, however Ghouri, as shown does:

- *configured to identify, characterize and rank adverse events caused by using a pharmaceutical product;* (see at least Ghouri [0090-0093])
- *determine whether the medication use process will be adequate to protect patients from a risk of experiencing adverse side effects associated with use of the pharmaceutical product;* (see at least Ghouri Claims:1-2, 18-19)
- *based on the determination . . . ;* (see at least Ghouri Claims:1-2, 18-19)
- *identify one or more multiple redundant interventions for each failure mode;* (see at least Ghouri Claims:4,7-13)

- *quantify the potential effect of said failure modes to create a pharmaceutical hazard score, wherein said hazard score considers the severity and frequency of occurrence of the effects of said failure modes;* (see at least Ghouri [0083-0090])
- *conduct a logical hazard assessment of said failure modes found to have a high hazard score to evaluate the need to mitigate the effect of said failure modes;* (see at least Ghouri [0083-0090])

It would have been obvious to one of ordinary skill in the art to add the feature of Ghouri into Mayaud. One of ordinary skill in the art would have added this feature into Mayaud with the motivation to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products. (see at least Ghouri Column:3 Lines:10-67 Column:4 Lines:1-42) Mayaud/Ghouri does not disclose the following limitation, however AOA, as shown does:

- *identify potential failure modes of the medication use process effects;* (see at least AOA [0002-0006])

It would have been obvious to one of ordinary skill in the art to add the features of AOA into Mayaud/Ghouri. One of ordinary skill in the art would have added these features into Mayaud/Ghouri with the motivation to provide an improved process for identifying and creating an ideal prescription plan in order to provide improved health care to patients.

Applicant's limitation, in claim 51: *wherein the medication use process is implemented to protect patients from a risk of experiencing adverse side effects associated with use of the pharmaceutical product;* is merely a recitation of the intended use of the claimed invention and is not given patentable weight to the extent that it imparts limitations to the invention, which are met by Beaulieu/Silva-Craig. (See MPEP 2111.04) A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim 52

Mayaud as shown, discloses the following limitations:

- *a processor;* (see at least Mayaud Fig:16 Items:201-218 & related text)
- *a memory operably connected to the processor, where the processor can access the memory;* (see at least Mayaud Fig:16 Items:201-218 & related text)
- *a logic operably connected to the processor;* (see at least Mayaud Claim:21-22, Fig:16 Items:201-218 & related text)
- *identify a medication use process associated with the pharmaceutical product;* (see at least Mayaud [0269-0270], Fig:6 Item:110-120 & related text)

- *design a risk management program to manage said adverse events wherein said risk management program comprises control measures to reduce the incidence and consequences of said failure modes;* (see at least Mayaud [0033], [0240-0246], Fig:15 Items:182-188 & related text)

Mayaud does not disclose the following limitations, however Ghouri, as shown does:

- *identify, characterize and rank adverse events caused by using a pharmaceutical product;* (see at least Ghouri [0090-0093])
- *determine whether the medication use process will be adequate to protect patients from experiencing adverse side effects;* (see at least Ghouri Claims:1-2, 18-19)
- *based on the determination . . . ;* (see at least Ghouri Claims:1-2, 18-19)
- *identify one or more multiple redundant interventions for each failure mode;* (see at least Ghouri Claims:4,7-13)
- *quantify the potential effect of said failure modes to create a pharmaceutical hazard score, wherein said hazard score considers the severity and frequency of occurrence of the effects of said failure modes;* (see at least Ghouri [0083-0090])
- *conduct a logical hazard assessment of said failure modes found to have a high hazard score to evaluate the need to mitigate the effect of said failure modes;* (see at least Ghouri [0083-0090])

It would have been obvious to one of ordinary skill in the art to add the feature of Ghouri into Mayaud. One of ordinary skill in the art would have added this feature into Mayaud with the motivation to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products. (see at least Ghouri Column:3 Lines:10-67 Column:4 Lines:1-42) Mayaud/Ghouri does not disclose the following limitation, however AOA, as shown does:

- *identify potential failure modes of the medication use process;* (see at least AOA [0002-0006])

It would have been obvious to one of ordinary skill in the art to add the features of AOA into Mayaud/Ghouri. One of ordinary skill in the art would have added these features into Mayaud/Ghouri with the motivation to provide an improved process for identifying and creating an ideal prescription plan in order to provide improved health care to patients.

Applicant's limitation, in claim 52: *wherein the medication use process is implemented to protect patients from a risk of experiencing adverse side effects associated with use of the pharmaceutical product;* is merely a recitation of the intended use of the claimed invention and is not given patentable weight to the extent that it imparts limitations to the invention, which are met by Beaulieu/Silva-Craig. (See MPEP 2111.04) A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior

art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim 53

Mayaud as shown, discloses the following limitations:

- *a processor;* (see at least Mayaud Fig:16 Items:201-218 & related text)
- *a computer-readable storage medium in communication with the processor the computer-readable storage medium including one or more programming instructions;* (see at least Mayaud [0018, 0342-344])
- *identifying a medication use process for the pharmaceutical product;* (see at least Mayaud [0269-0270], Fig:6 Item:110-120 & related text)
- *by the processor;* (see at least Mayaud Fig:16 Items:201-218 & related text)
- *designing a risk management program to manage said adverse events wherein said risk management program comprises control measures to reduce the incidence and consequences of said failure modes;* (see at least Mayaud [0033], [0240-0246], Fig:15 Items:182-188 & related text)

Mayaud does not disclose the following limitations, however Ghouri, as shown does:

- *identifying adverse events caused by using the pharmaceutical product;* (see at least Ghouri [0090-0093])

- *determining, . . . , whether the medication use process will be adequate to protect patients from experiencing adverse side effects;* (see at least Ghouri Claims:1-2, 18-19)
- *based on the determination . . . ;* (see at least Ghouri Claims:1-2, 18-19)
- *identify one or more multiple redundant interventions for each failure mode;* (see at least Ghouri Claims:4,7-13)
- *quantifying the potential effect of said failure modes to create a pharmaceutical hazard score, wherein said hazard score considers the severity and frequency of occurrence of the effects of said failure modes;* (see at least Ghouri [0083-0090])
- *conducting a logical hazard assessment of said failure modes found to have a high hazard score to evaluate the need to mitigate the effect of said failure modes;* (see at least Ghouri [0083-0090])

It would have been obvious to one of ordinary skill in the art to add the feature of Ghouri into Mayaud. One of ordinary skill in the art would have added this feature into Mayaud with the motivation to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products. (see at least Ghouri Column:3 Lines:10-67 Column:4 Lines:1-42) Mayaud/Ghouri does not disclose the following limitation, however AOA, as shown does:

- *identifying potential failure modes of the medication use process;* (see at least AOA [0002-0006])

It would have been obvious to one of ordinary skill in the art to add the features of AOA into Mayaud/Ghouri. One of ordinary skill in the art would have added these features into Mayaud/Ghouri with the motivation to provide an improved process for identifying and creating an ideal prescription plan in order to provide improved health care to patients.

Applicant's limitation, in claim 53: *wherein the medication use process is implemented to protect patients from a risk of experiencing adverse side effects associated with use of the pharmaceutical product;* is merely a recitation of the intended use of the claimed invention and is not given patentable weight to the extent that it imparts limitations to the invention, which are met by Beaulieu/Silva-Craig. (See MPEP 2111.04) A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

18. Claims 2-6, 26-27, 41 & 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayaud in view of Ghouri in view of AOA in further view of Ousdigian et al. (US 6438407 B1) (hereinafter Ousdigian).

Claim 2

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1. Ousdigian further discloses the following limitation:

- *implementing said risk management program;* (see at least Ousdigian Column:2 Lines:9-64)

It would have been obvious to one of ordinary skill in the art to add the feature of Ousdigian into Mayaud/Ghouri/AOA. One of ordinary skill in the art would have added this feature into Mayaud/Ghouri/AOA with the motivation to more accurately measure medical statistics in a patient's medical plan and more effectively administer an individually tailored medical regimen. (see at least Ousdigian Column:2 Lines:4-64)

Claim 3

The combination of Mayaud/Ghouri/AOA/Ousdigian disclose all the limitations of claim 2. Ousdigian further discloses the following limitation:

- *measuring the effectiveness of said risk management program;* (see at least Ousdigian Column:2 Lines:9-64)

It would have been obvious to one of ordinary skill in the art to add the feature of Ousdigian into Mayaud/Ghouri/AOA/Ousdigian. One of ordinary skill in the art would have added this feature into Mayaud/Ghouri/AOA/Ousdigian with the motivation to more accurately measure medical statistics in a patient's medical plan and more effectively administer an individually tailored medical regimen. (see at least Ousdigian Column:2 Lines:4-64)

Claim 4

The combination of Mayaud/Ghouri/AOA/Ousdigian disclose all the limitations of claim 3. Ghouri further discloses the following limitation:

- *measuring and defining metrics, measurement systems, program goals, objectives and program performance analysis and reporting;* (see at least Ghouri Fig:2 & related text)

It would have been obvious to one of ordinary skill in the art to add the feature of Ousdigian into Mayaud/Ghouri/AOA/Ousdigian. One of ordinary skill in the art would have added this feature into Mayaud/Ghouri/AOA/Ousdigian with the motivation to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products. (see at least Ghouri Column:3 Lines:10-67 Column:4 Lines:1-42)

Claim 5

The combination of Mayaud/Ghouri/AOA/Ousdigian disclose all the limitations of claim 3. Ghouri further discloses the following limitation:

- *integrating said effectiveness measurement into said pharmaceutical product hazard score;* (see at least Ghouri [0076-0087], [0090-0094])

It would have been obvious to one of ordinary skill in the art to add the feature of Ousdigian into Mayaud/Ghouri/AOA/Ousdigian. One of ordinary skill in the art would have added this feature into Mayaud/Ghouri/AOA/Ousdigian with the motivation to more accurately and effectively assess, analyze, score, and identify

the different aspects of pharmaceutical products. (see at least Ghouri Column:3 Lines:10-67 Column:4 Lines:1-42)

Claim 6

The combination of Mayaud/Ghouri/AOA/Ousdigian disclose all the limitations of claim 5. Ousdigian further discloses the following limitation:

- *reporting said effectiveness measurement;* (see at least Ousdigian Column:2 Lines:16-28)

It would have been obvious to one of ordinary skill in the art to add the feature of Ousdigian into Mayaud/Ghouri/AOA/Ousdigian. One of ordinary skill in the art would have added this feature into Mayaud/Ghouri/AOA/Ousdigian with the motivation to more accurately measure medical statistics in a patient's medical plan and more effectively administer an individually tailored medical regimen. (see at least Ousdigian Column:2 Lines:4-64)

Claim 26

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1. Ousdigian further discloses the following limitation:

- *implementing human behavior changing interventions;* (see at least Ousdigian Column:2 Lines:9-64)

It would have been obvious to one of ordinary skill in the art to add the feature of Ousdigian into Mayaud/Ghouri/AOA/Ousdigian. One of ordinary skill in the art would have added this feature into Mayaud/Ghouri/AOA/Ousdigian with the motivation to more accurately measure medical statistics in a patient's medical

plan and more effectively administer an individually tailored medical regimen. (see at least Ousdigian Column:2 Lines:4-64)

Claim 27

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1. Ousdigian further discloses the following limitation:

- *utilizing disease management approaches, principles, methods, techniques and tools to change end user behavior;* (see at least Ousdigian Column:2 Lines:9-64)

It would have been obvious to one of ordinary skill in the art to add the feature of Ousdigian into Mayaud/Ghouri/AOA/Ousdigian. One of ordinary skill in the art would have added this feature into Mayaud/Ghouri/AOA/Ousdigian with the motivation to more accurately measure medical statistics in a patient's medical plan and more effectively administer an individually tailored medical regimen. (see at least Ousdigian Column:2 Lines:4-64)

Claim 41

The combination of Mayaud/Ghouri/AOA disclose all the limitations of claim 1. Ousdigian further discloses the following limitation:

- *mandating periodic or intermittent tests for the existence of contraindications for the pharmaceutical product;* (see at least Ousdigian Column:2 Lines:9-64)

It would have been obvious to one of ordinary skill in the art to add the feature of Ousdigian into Mayaud/Ghouri/AOA/Ousdigian. One of ordinary skill in the art

would have added this feature into Mayaud/Ghouri/AOA/Ousdigian with the motivation to more accurately measure medical statistics in a patient's medical plan and more effectively administer an individually tailored medical regimen. (see at least Ousdigian Column:2 Lines:4-64)

Claim 54

Mayaud as shown, discloses the following limitations:

- *a computer means for identifying a medication use process for the pharmaceutical product;* (see at least Mayaud [0269-0270], Fig:6 Item:110-120 & related text)
- *a computer means for designing a risk management program to manage said adverse events wherein said risk management program comprises control measures to reduce the incidence and consequences of said failure modes;* (see at least Mayaud [0033], [0240-0246], Fig:15 Items:182-188 & related text)

Mayaud does not disclose the following limitations, however Ghouri, as shown does:

- *a computer means for identifying adverse events caused by using the pharmaceutical product;* (see at least Ghouri [0090-0093])
- *a computer means for determining whether the medication use process will be adequate to protect patients from experiencing adverse side effects;* (see at least Ghouri Claims:1-2, 18-19)

- *based on the determination . . . ;* (see at least Ghouri Claims:1-2, 18-19)
- *identifying one or more multiple redundant interventions for each failure mode;* (see at least Ghouri Claims:4,7-13)
- *a computer means for quantifying the potential effect of said failure modes to create a pharmaceutical hazard score, wherein said hazard score considers the severity and frequency of occurrence of the effects of said failure modes;* (see at least Ghouri [0083-0090])
- *a computer means for conducting a logical hazard assessment of said failure modes found to have a high hazard score to evaluate the need to mitigate the effect of said failure modes;* (see at least Ghouri [0083-0090])

It would have been obvious to one of ordinary skill in the art to add the feature of Ghouri into Mayaud. One of ordinary skill in the art would have added this feature into Mayaud with the motivation to more accurately and effectively assess, analyze, score, and identify the different aspects of pharmaceutical products. (see at least Ghouri Column:3 Lines:10-67 Column:4 Lines:1-42) Mayaud/Ghouri does not disclose the following limitation, however AOA, as shown does:

- *a computer means for identifying, . . . , potential failure modes of the medication use process;* (see at least AOA [0002-0006])

It would have been obvious to one of ordinary skill in the art to add the features of AOA into Mayaud/Ghouri. One of ordinary skill in the art would have

added these features into Mayaud/Ghouri with the motivation to provide an improved process for identifying and creating an ideal prescription plan in order to provide improved health care to patients.

Mayaud/Ghouri/AOA does not disclose the following limitation, however Ousdigian, as shown does:

- *a computer means for measuring, evaluating and reporting the effectiveness of a risk management program.;* (see at least Ousdigian Column:2 Lines:9-64)

It would have been obvious to one of ordinary skill in the art to add the feature of Ousdigian into Mayaud/Ghouri/AOA. One of ordinary skill in the art would have added this feature into Mayaud/Ghouri/AOA with the motivation to more accurately measure medical statistics in a patient's medical plan and more effectively administer an individually tailored medical regimen. (see at least Ousdigian Column:2 Lines:4-64)

Applicant's limitation, in claim 54: *wherein the medication use process is implemented to protect patients from a risk of experiencing adverse side effects associated with use of the pharmaceutical product;* is merely a recitation of the intended use of the claimed invention and is not given patentable weight to the extent that it imparts limitations to the invention, which are met by Beaulieu/Silva-Craig. (See MPEP 2111.04) A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior

art. If the prior art structure is capable of performing the intended use, then it meets the claim.

19. Claims 22, 28 & 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayaud in view of Ghouri in view of AOA in further view of Official Notice.

Claim 22

The combination of Mayaud/Ghouri/AOA discloses all of the limitations of claim 1. The combination of Mayaud/Ghouri/AOA does not specifically disclose *utilizing one or more of adult learning principles, enablers, personal application, multiple media, repetitive messaging, self assessments, feedback, incentives and consequence messages.* However, the Examiner takes **Official Notice** that it is old and well known in the medical arts to employ such techniques when administering an effective health program. It would have been obvious to one skilled in the art at the time of the invention to combine the limitations of Mayaud/Ghouri/AOA with *utilizing one or more of adult learning principles, enablers, personal application, multiple media, repetitive messaging, self assessments, feedback, incentives and consequence messages* because such practices are standard and necessary aspects of implementing any type of health assessment program.

Claim 28

The combination of Mayaud/Ghouri/AOA discloses all of the limitations of claim 1. The combination of Mayaud/Ghouri/AOA does not specifically disclose *integrating risk messages into promotional materials of the pharmaceutical product.* However, the Examiner takes **Official Notice** that it is old and well known in the medical arts to employ such techniques when distributing health-related products. It would have been obvious to one skilled in the art at the time of the invention to combine the limitations of Mayaud/Ghouri/AOA with *integrating risk messages into promotional materials of the pharmaceutical product* because such practices are standard and necessary to conform to the requirements of distributing pharmaceutical products.

Claim 37

The combination of Mayaud/Ghouri/AOA discloses all of the limitations of claim 35. The combination of Mayaud/Ghouri/AOA does not specifically disclose *limiting availability of the pharmaceutical product to authorized pharmacies.* However, the Examiner takes **Official Notice** that it is old and well known in the medical arts to employ such techniques when distributing health-related products. It would have been obvious to one skilled in the art at the time of the invention to combine the limitations of Mayaud/Ghouri/AOA with *limiting availability of the pharmaceutical product to authorized pharmacies* because such practices are a standard, necessary and required practice when distributing pharmaceutical products.

Claim 38

The combination of Mayaud/Ghouri/AOA discloses all of the limitations of claim 35. The combination of Mayaud/Ghouri/AOA does not specifically disclose *requiring a pharmacist to be certified to dispense the pharmaceutical product.* However, the Examiner takes **Official Notice** that it is old and well known in the medical arts to employ such techniques when distributing health-related products. It would have been obvious to one skilled in the art at the time of the invention to combine the limitations of Mayaud/Ghouri/AOA with *requiring a pharmacist to be certified to dispense the pharmaceutical product* because such practices are a standard, necessary and required practice when distributing pharmaceutical products.

Claim 39

The combination of Mayaud/Ghouri/AOA discloses all of the limitations of claim 35. The combination of Mayaud/Ghouri/AOA does not specifically disclose *limiting physician prescribing rights.* However, the Examiner takes **Official Notice** that it is old and well known in the medical arts to employ such techniques when distributing health-related products. It would have been obvious to one skilled in the art at the time of the invention to combine the limitations of Mayaud/Ghouri/AOA with *limiting physician prescribing rights* because such practices are a standard, necessary and required practice when distributing pharmaceutical products.

Claim 40

The combination of Mayaud/Ghouri/AOA discloses all of the limitations of claim 35. The combination of Mayaud/Ghouri/AOA does not specifically disclose *limiting the number of refills per prescription, limiting the expiration date of a prescription, and/or limiting the form of a prescription.* However, the Examiner takes **Official Notice** that it is old and well known in the medical arts to employ such techniques when distributing health-related products. It would have been obvious to one skilled in the art at the time of the invention to combine the limitations of Mayaud/Ghouri/AOA with *limiting the number of refills per prescription, limiting the expiration date of a prescription, and/or limiting the form of a prescription* because such practices are a standard, necessary and required practice when distributing pharmaceutical products.

Claim 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayaud in view of Ghouri in view of AOA in view of Ousdigian in further view of Official Notice.

Claim 42

The combination of Mayaud/Ghouri/AOA/Ousdigian discloses all of the limitations of claim 41. The combination of Mayaud/Ghouri/AOA/Ousdigian does not specifically disclose *contraindications comprise pregnancy.* However, the Examiner takes **Official Notice** that it is old and well known in the medical arts to employ such techniques when distributing health-related products. It would have been obvious to one skilled in the art at the time of the invention to combine the

limitations of Mayaud/Ghouri/AOA/Ousdigian with *contraindications comprise pregnancy* because such practices are a standard, necessary and required practice when distributing pharmaceutical products.

Response to Arguments

20. Applicant's arguments filed 23 September 2009 have been fully considered but they are not persuasive. Applicants' arguments will be addressed herein below in the order in which they appear in the response filed 23 September 2009.

21. In response to applicant's regarding the following claim language: "*determining, by the processor, whether the medication use process will be adequate to protect patients from experiencing adverse side effects; and based on the determination, identifying potential failure modes where the medication use process will not be adequate to protect patients from experiencing adverse side effects and identifying one or more multiple redundant interventions for each failure mode*", the Examiner points out that his claim language was added in the most recent claims, and is appropriately dealt with in the current Office Action.

22. In response to applicant's argument that cited prior art is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).

23. In response to applicant's argument that the Ghouri fails to "describe any medication use process", the Examiner has fully considered applicant's arguments and finds them unpersuasive and unsubstantiated.
24. In response to applicant's argument that the AOA fails to "suggest identifying potential failure modes where the medication use process will not be adequate to protect patients from experiencing adverse side effects . . . ", the Examiner respectfully disagrees in light of the cited prior art (see at least AOA [0002-0006] "identify all potential adverse events, this methodology utilizes a weighted analysis to address only what are deemed to be the most undesirable of the adverse events. Once these adverse events are identified, the analysis turns to identifying and evaluating the potential failures in the system which may lead to those events").
25. Applicant's arguments for 2-42 are based on their dependency of claim 1 and thus are rejected on the same grounds.
26. In response to applicant's regarding the new claim language, in claims 51-52 & 54, the Examiner points out that his claim language was added in the most recent claims, and is appropriately dealt with in the current Office Action.

Definitions

The Examiner hereby adopts the following definitions under the broadest reasonable interpretation standard. In accordance with *In re Morris,* 127 F.3d 1048, 1056, 44

USPQ2d 1023, 1029 (Fed. Cir. 1997), the Examiner points to these other sources to support his interpretation of the claims.[1] Additionally, these definitions are only a guide to claim terminology since claim terms must be interpreted in context of the surrounding claim language. Finally, the following list is not intended to be exhaustive in any way:

computer "Any machine that does three things: accepts structured input, processes it according to prescribed rules, and produces the results as output." Computer Dictionary, 3rd Edition, Microsoft Press, Redmond, WA, 1997.

medium "A substance in which signals can be transmitted." Computer Dictionary, 5th Edition, Microsoft Press, Redmond, WA, 2002.

memory "A device where information can be stored and retrieved. In the most general sense, memory can refer to external storage such as disk drives or tape drives; in common usage it refers only to the fast semiconductor storage (RAM) directly connected to the processor." Computer Dictionary, 3rd Edition, Microsoft Press, Redmond, WA, 1997.

memory "A device where information can be stored and retrieved." Computer Dictionary, 5th Edition, Microsoft Press, Redmond, WA, 2002.

network "(3) (A) (software) An interconnected or interrelated group of nodes." IEEE 100 The Authoritative Dictionary of IEEE Standards Terms, 7th Edition, IEEE, Inc., New York, NY, Dec. 2000.

---

[1] While most definition(s) are cited because these terms are found in the claims, the Examiner may have provided additional definition(s) to help interpret words, phrases, or concepts found in the definitions themselves or in the prior art.

processor "(2) (software) A computer program that includes the compiling, assembling, translating, and related functions for a specific programming language, for example, Cobol processor, Fortran processor." IEEE 100 The Authoritative Dictionary of IEEE Standards Terms, 7th Edition, IEEE, Inc., New York, NY, Dec. 2000.

storage media "The various types of physical material on which data bits are written and stored, such as floppy disks, hard disks, tape, and optical discs." Computer Dictionary, 5th Edition, Microsoft Press, Redmond, WA, 2002.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RAJIV J. RAJ whose telephone number is (571) 270-3930. The examiner can normally be reached on Monday thru Friday 8-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

Date: 11/31/09
/RJR/ Patent Examiner Art Unit 3686

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686